RMD NAVIGATOR GPS* System

ENGLISH

Operating / Service Manual

RMD

GP-6800-10

ENGLISH

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1 Introduction

CAUTION: Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.

Description

The NAVIGATOR GPS Gamma Positioning System is a portable, battery powered system that detects gamma photons, such as are produced by radioactive decay. The system includes five principal items:

- one or more probes,
- control unit,
- cable which connects each probe to the control unit,
- power pak, and
- charger.

The general configuration of the NAVIGATOR GPS System is the control unit connected to the hand-held probe by means of the cable. The control unit allows the user to adjust the system's controls and produces a variety of signal outputs. The control unit is powered by a power pak in the control unit. The charger connects to the power pak removed from the control unit, or to a spare power pak. The system is supplied non-sterile. This manual includes guidelines for the use of the probe and cable in the sterile field.

Indications for Use

For the detection and quantification of gamma radiation from gamma-emitting isotopes in the body or tissues. Use for non-imaging procedures to measure the amount of radionuclide absorbed by a particular organ or body region in open-surgical, *laparoscopic* or *thoracoscopic* surgical procedures.

Manufacture and Distribution

The system is manufactured and distributed by RMD Instruments, LLC. Please direct all inquiries about the RMD NAVIGATOR GPS* System to RMD Instruments, LLC.

Standards

The RMD NAVIGATOR GPS* System complies with the following standards:

EMC Directive:
EC Directive 89/336/EEC
Group 1, Class B
EN 55011

EMC Directive *89/336/EEC*
EN 60601-1-2: 1993

Safety:
IEC 601-1, 2nd Edition, "Safety Requirements for Medical Equipment" in accordance with the procedures of the international CB scheme

EN60601-1: 1990 "Medical Electrical Equipment, Part 1: General Requirements for Safety" including Amendments Al + A2

UL260 1-1 "Medical Electrical Equipment, Part 1: General Requirements for Safety" 2nd Edition including Amendments 1 and 2

CAN/CSA C22.2 No. 601.1 -M90, "Medical Electrical Equipment, Part 1: General Requirements for Safety, including C22.2 NO. 601.IS1-94 (IEC6O1-1, Amendment 1:1991) Supplement No. 1-94 to CAN/CSA 22.2 No. 601-1-M90"

AS/NZS 3200-1-0, Deviations to IEC 601-1 for Application in Australia and New Zealand

IEC 601-1-1, 1st Edition "Safety Requirements for Medical Electrical Systems"

Other:

C E Listing

Year 2000 compliance

2 Operating Precautions

General

- The output of this system is not to be considered the sole diagnostic measure of the extent of disease in the patient, nor the sole source of recommended therapy.
- Failure to thoroughly review and adhere to the information contained in this operating manual, including specifically the following operating precautions, may pose a potential hazard to the patient and/or user and may void the Warranty.

Probe and Cable

- Probe and Cable sterilization should be done by ethylene oxide only. In this procedure, the probe is separated from the cable and each is sterilized as individual items.
- During ethylene oxide sterilization, do not exceed 60°C (140°F). Temperatures above 60°C may permanently damage the probe.
- Do not put the probe or cable in an autoclave.
- Do not open the probe. The probe is tested and sealed at the factory. Attempts to open the probe may damage the probe and will void the warranty.
- Do not drop the Probe or strike the probe tip against hard surfaces. Damage to the detector element and inability of the probe to measure radiation may result. This may also void the warranty.

Control Unit, Power Pak and Charger

- During system use, maintain electrical isolation of the patient. Do not connect either the probe, the cable, or the internal circuit of the control unit to earth ground, or to other voltage potentials.
- Maintain patient isolation. Do not defeat the electrical isolation provided by the surface of the probe cable and the housing of the control unit. These items isolate other voltage potentials from the battery-powered circuit inside the control unit, the inside of the probe cable, the surface of the probe, and the patient.
- Do not defeat the electrical isolation between the external DATA PORT on the control unit and the circuit inside the control unit. The external DATA PORT can be connected to earth ground. The electrical isolation between the data port and the internal circuit of the control unit maintains patient isolation.
- When optional system components are used with the system, maintain probe and patient electrical-isolation from earth ground, as described by this and other precautions in the Operating Manual. These optional components include the CoPilot* device, the gamma probe drape, and the custom cart.
- The charger has a rating in the United States of a "patient proximity charger" and when it is used in the operating room, the charger must be used at a distance of greater than six feet from the patient.
- Fully charge the power pak before use in the system.
- This equipment is not designed for use in an explosive atmosphere.
- Place the control unit power switch in the OFF position when changing the Power Pak, and when changing connections between the probe, the cable, and the control unit.
- The control unit, power pak, and charger are non-sterile. Do not sterilize these components.

Operating Precautions continued

- IMPORTANT: This booklet is designed to assist in using the Navigator device. It is not a reference to surgical techniques. For information on endoscopic procedures, techniques, complications and hazards please see the books: Surgical Laparoscopy (Zuker KA ed. St. Louis MO 1991) and Endoscopic Surgery (White RA Klein SR. Mosby Year Book Inc. St. Louis MO 1991).

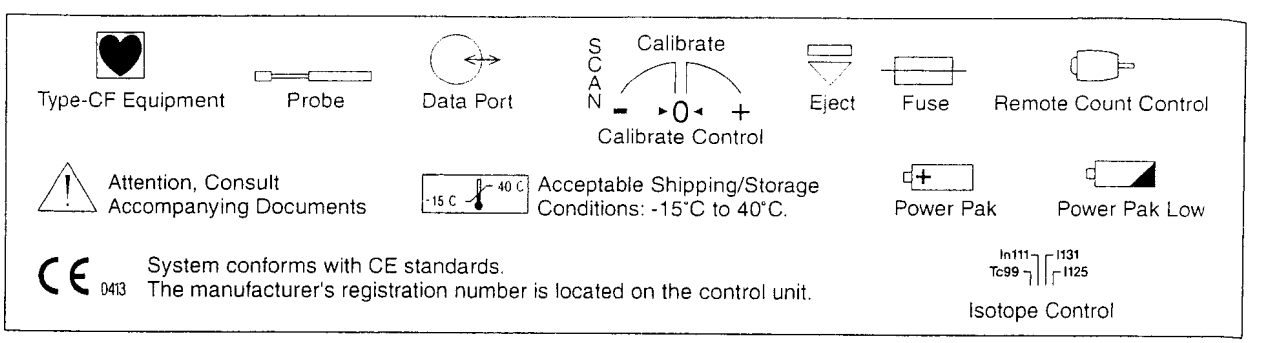
- CAUTION: Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques in addition medical literature should be consulted relative to techniques, complications and hazards prior to the performance of endoscopic procedures.

- CONTRAINDICATIONS: This device is intended for use only as indicated. It is not intended for use when endoscopic techniques are generally contraindicated. Please see the book: Textbook of Laparoscopy (Hulka JF. Grunda and Straton, Inc. Orlando FL 1985 op 114-116) for information on Absolute Contraindications, High-Risk Patients and Low-Risk Patients.

- The use of the Navigator GPS system with laparoscopy should only be attempted where there is adequate visualization of the target tissue.

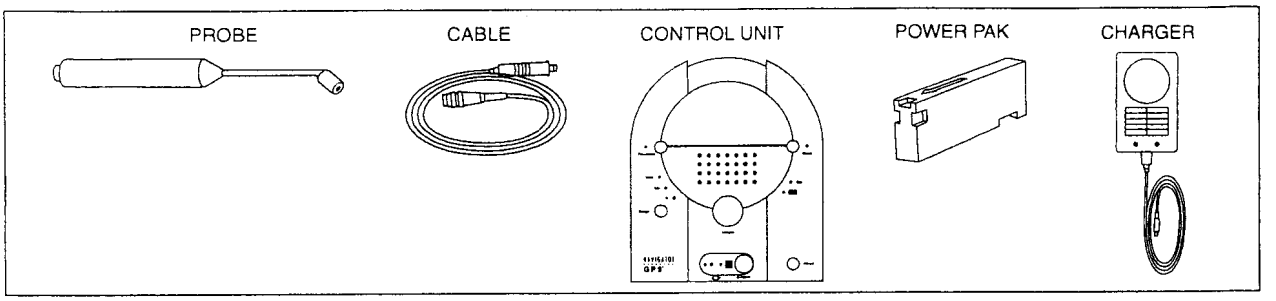
- Trocars should be placed in accordance with standard laparoscopic and thoracoscopic techniques with specific regard to target organ geometry to assure probe access to the target organ. Please reference current Trocar labeling suggesting working knowledge of laparoscopic techniques and familiarization with trocar placements under direct visualization through a laparoscope.

Explanation of Symbols



3 Controls and Specifications

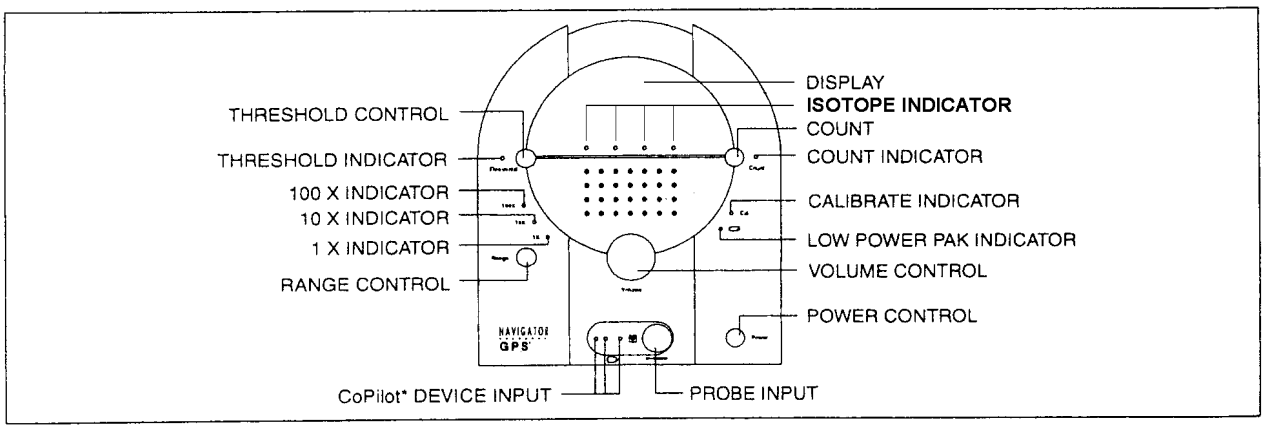
System Components



SYSTEM COMPONENTS include the CONTROL UNIT, PROBE, CABLE, POWER PAK, and CHARGER.

Control Unit

Front Panel Controls and Indicators



DISPLAY

The normal mode of the DISPLAY shows the number of photons, also called events, that the system detects each second. Expressed differently, the DISPLAY shows "counts per second."

If the COUNT button is pressed on the CONTROL UNIT, a ten second counting period begins and the DISPLAY shows a continuously increasing number of events. When the time period is complete, the total number of events is shown in the DISPLAY for four seconds, after which the DISPLAY returns to the normal mode of showing counts per second.

The CoPilot* Device ACCESSORY has the ability to initiate either a one-second count, or a ten second count, the total of which is shown in the DISPLAY, and also downloaded to the DATA PORT.

The value shown in the DISPLAY is not affected by either the RANGE control or the VOLUME control. The value shown in the DISPLAY is affected by the THRESHOLD control and the ISOTOPE control.

THRESHOLD

The Energy THRESHOLD control selects between two ranges of photon energies detected by the probe: 1) a selective energy window, and 2) a wide energy window.

With the THRESHOLD enabled, or ON, the system places an energy window around the photopeak energy of the isotope indicated by the rear-panel, ISOTOPE control. Only those signals from the probe that are within the

energy window are processed by the system. A scattered photon leaves the isotope with a particular energy and direction, and interacts (Compton scatters) with tissue or other material. The resulting, *scattered* photon proceeds with a lower energy in a new direction. With the threshold ON, the principal advantage is that scattered photons are reduced or eliminated from the system signal. Additional ways of saying that the threshold is ON, is that the threshold is "active" or the threshold is "enabled".

With the THRESHOLD inactive, or OFF, the full range of photon energies detected by the probe are processed by the system. The resulting event rate is presented to the DISPLAY, the audible PITCH output, and the DATA PORT. Typically, more events are detected when the THRESHOLD is OFF, than when ON. The THRESHOLD OFF position of this control is also a useful configuration of the system for detecting isotopes within the system capabilities and beyond the choices available on the rear-panel ISOTOPE control.

THRESHOLD INDICATOR

Illuminates when the energy THRESHOLD is active or ON. The THRESHOLD INDICATOR is OFF when the THRESHOLD is disabled, or OFF, and the full range of energies detected by the probe are processed by the system.

PITCH

The PITCH is an audible signal produced by the system and indicates the events (also called photons) detected by the system. The higher the PITCH (or tone), the greater the event rate. Changes in PITCH relate to changes in EVENT rates. The principal controls used to adjust the PITCH signal are the RANGE control and the VOLUME control.

RANGE

The RANGE control allows the user to select the audible PITCH range appropriate to the event rate seen by the system. Each time the RANGE control is pressed and released, the system moves to the next range.

The RANGE control does not affect either the DISPLAY or the DATA PORT. The RANGE control affects only the audible PITCH output. The user can quickly cycle through the RANGE positions and find the most useful RANGE setting.

1 X INDICATOR

Illuminates when the 1 X audible RANGE is selected. In this RANGE setting, the audible PITCH signal relates to low event rates. For example, the user may observe that each event detected by the system is instantaneously represented in the PITCH signal.

10 X INDICATOR

Illuminates when the 10 X audible RANGE is selected. This RANGE setting is useful at intermediate event rates.

100 X INDICATOR

Illuminates when the 100 X audible RANGE is selected. In this RANGE setting, the audible PITCH indicates high event rates. Changes in PITCH relate to changes in high event rates.

VOLUME

The VOLUME control adjusts the volume of the audible PITCH. The full counter clockwise position is minimum.

CoPilot* Device INPUT

This receptacle on the CONTROL UNIT accepts the CONNECTOR of the optional CoPilot* DEVICE accessory. The receptacle has a coded-spacing of three sockets so that the unique CONNECTOR of the CoPilot* DEVICE accessory is identified and aligned properly. Slide the CONNECTOR securely into the receptacle on the CONTROL UNIT.

PROBE INPUT

This front panel receptacle accepts the CABLE from the PROBE. There is a male plug on the CABLE and a female receptacle on the CONTROL UNIT. The connector is a locking connector. Tension on the cable will not pull the cable from the CONTROL UNIT.

- Place the CONTROL UNIT's POWER switch OFF when changing this connection.

- To connect the CABLE to the CONTROL UNIT, align the keyed connector with the receptacle, and lightly insert the plug into the receptacle. A slight audible click may be heard when the plug locks in place.
- To disconnect the CABLE from the CONTROL UNIT, grasp the CONNECTOR and gently pull the CONNECTOR from the control unit. Tension on the CONNECTOR retracts the plug's internal locking mechanism and allows the plug to be removed from the CONTROL UNIT.

POWER

The CONTROL button toggles between two positions: ON and OFF. Press and release the POWER button to change the condition.

NOTE: Place the POWER switch OFF when changing the Power Pak, changing the fuse, disconnecting or connecting the PROBE to the CABLE, and when connecting or disconnecting the CABLE to the CONTROL UNIT.

When the POWER is ON, at least one of the digits in the display is illuminated. Please ensure that the control UNIT is properly equipped with a charged power pak and the recommended FUSE.

COUNT

Press and release the COUNT control button to begin a ten second counting period. The CONTROL UNIT instantly begins counting. The DISPLAY updates immediately with each new, detected event.

At the end of the counting period, the CONTROL UNIT gives a brief audible signal. The total value is shown in the DISPLAY for approximately four seconds. The system then returns to its normal display mode of showing "counts per second".

COUNT INDICATOR

This indicator is illuminated when a counting period is active.

ISOTOPE INDICATOR

Four ISOTOPE INDICATORS are located inside the DISPLAY. With the POWER ON, one of the ISOTOPE INDICATORS is illuminated and corresponds to the position of the rear-panel ISOTOPE CONTROL. For example, when "Tc99" is selected on the rear-panel control, the "Tc99" indicator is illuminated on the front panel.

Note: With any of the five probes described on page nine of this manual and the I131 position selected on the rear-panel ISOTOPE control, the probe and control unit detect 364 keV photons from the isotope I131.

An RMD probe for 511 keV is required to detect 511 keV photons produced by fluorodeoxyglucose (FDG) and other PET pharmaceuticals. The 511 keV PROBE connects to the CONTROL UNIT. The ISOTOPE control is placed in the "I131" position. The ISOTOPE indicator of "511keV & I131" is illuminated. Examples:

ISOTOPE	PROBE	ISOTOPE CONTROL	ISOTOPE INDICATOR
Technetium-99m	Standard Lymphatic Mapping Probe	Tc99	Tc99
Iodine-125	Standard Lymphatic Mapping Probe	I125	I125
Indium-111	Standard Lymphatic Mapping Probe	I111	I111
Iodine-131	Standard Lymphatic Mapping Probe	I131	511keV & I131
FDG	RMD Probe for 511 keV	I131	511keV & I131

CALIBRATE INDICATOR

This indicator is OFF during normal use of the system. This indicator blinks ON and OFF when the rear-panel CALIBRATE control is in a test position. The user may perform a calibration check of the system which involves the CALIBRATE control and an isotopic source of cobalt-57. For normal system use, keep the rear-panel CALIBRATE control in the SCAN position.

LOW POWER PAK INDICATOR

This indicator is OFF during normal use of the system. (This indicator is also OFF when the POWER PAK is completely discharged, the fuse needs replacement, or the POWER switch is OFF.)

The LOW POWER PAK INDICATOR blinks ON and OFF when the system is on, and only 15 to 30 minutes of useful charge remains on the system POWER PAK. The LOW POWER PAK INDICATOR stays ON continuously for a short period of time before the remaining, useful charge of the POWER PAK is exhausted.

The CONTROL UNIT may be turned off, the existing POWER PAK removed, a charged POWER PAK placed in the system, and the CONTROL UNIT turned back ON.

Rear Panel, Side Panel, and Bottom Panel Controls and Indicators

ISOTOPE

The rear panel ISOTOPE control allows the user to select the isotope to which the selective energy window of the THRESHOLD control applies.

The ISOTOPE control includes positions for: technetium-99m, iodine-125, indium-111, and iodine-131. Because the most-frequently used isotope is technetium-99m, the ISOTOPE control is most-frequently kept in the technetium-99m position.

When the THRESHOLD control is ON, the system detects photons in a narrow energy window about the peak energy of the isotope indicated by the ISOTOPE control. When the THRESHOLD control is OFF, the narrow energy window is disabled and the wide range of photon energies which the system is capable of processing are counted by the system.

NOTE: Keep the ISOTOPE control in the technetium-99m position to maintain system configuration (including energy selection by the THRESHOLD control) for detecting technetium-99m.

CALIBRATE

The rear panel CALIBRATE control has four positions: SCAN, BELOW (−), CENTERED (▸0◂), and ABOVE (+).

The CALIBRATE control is kept in the SCAN position for routine system use. With the CALIBRATE control in this position, the front-panel, CALIBRATE INDICATOR is OFF.

A system calibration check is performed with the CALIBRATE control moved among the test positions of BELOW (−), CENTERED (▸0◂), and ABOVE (+). The calibration check requires a cobalt-57 reference source. With the CALIBRATE control in a test position, the front panel CALIBRATE INDICATOR blinks ON and OFF. To restore the system for normal use, place the rear-panel CALIBRATE control in the SCAN position.

DATA PORT

Immediately following each timed count, the six digit count total is available from the DATA PORT on the rear panel of the control unit. The control unit transmits four bytes of data, then returns to normal condition. A description of the digital coding of the DATA PORT is described elsewhre in this manual.

NOTE: The DATA PORT is "send-only." The NAVIGATOR GPS* System is not constructed to "receive" any information through the DATA PORT.

POWER PAK EJECT

The POWER PAK EJECT is a mechanical lever on the side of the control unit. With the CONTROL UNIT resting on a horizontal surface, press the power pak EJECT button to release the power pak from the CONTROL UNIT. Slide the power pak out of the CONTROL UNIT. When a power pak is placed securely in the control unit, the POWER PAK EJECT button latches into place.

POWER PAK PORT

This is the mechanical opening on the side of the unit through which the POWER PAK is slid into the CONTROL UNIT.

FUSE RECEPTACLE

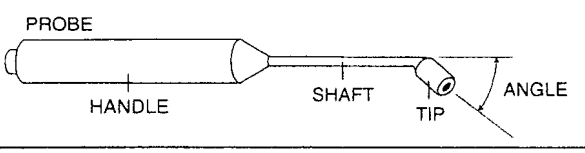
The FUSE RECEPTACLE is located on the bottom of the control unit. The receptacle is opened by a counter-clockwise rotation of the end cap. The fuse may be inspected, and replaced, if necessary, by a FUSE described in the chart of control unit specifications. Secure the FUSE in place by a clockwise rotation of the FUSE RECEPTACLE.

Control Unit Specifications

Control Unit Operating Power Source	Replaceable, internal power pak
Power Pak	Sealed, lead-acid, rechargeable. 12 V (nominal) voltage. 2.0 Ah (nominal) capacity. 590 grams approximate weight.
Fuse - Control Unit	UL/CSA (198G) standards: 0.75 ampere. Slow-Blow. Glass housing. 250 volt rating. 5 x 20 mm IEC127 standards: Type T. 0.63 ampere 250 volts 5 x 20 mm T0.63AL250V
New Power Pak Charge life (at full charge)	4 hours continuous (nominal)
Power Pak Recharge Cycles (for 100% discharge)	150-200 cycles (to 80% of new power pak charge life)
Sound Indicators	**Pitch** - sound. Frequency proportional to event rate. **Beep** - Indicates need to recharge batteries. Occurs when RECHARGE indicator turns on.
Visual Indicators	**Digital Count** - Vacuum Fluorescent Display **Single Count** - LED indicator **Sample Time Active** - LED indicator **Power Pak Low** - LED indicator **Power Pak Recharge Required** - LED indicator **Range 1X, 10X, and 100X** - LED indicators **Isotope Indicator** - LED indicator (four)
Energy Range	Up to and including 511 keV
Storage Conditions	-15°C to 40°C, 0% to 80% relative humidity
Maximum Count Rate	25,000 counts per second
Control Unit Dimensions	20 cm wide x 24 cm tall x 18 cm deep
Control Unit Weight (power pak installed)	2.0 kg

Probe

Probe Features



Probe Specifications

Name	Tip Diameter	Angle	Shaft Length
Standard Lymphatic Mapping Probe	14 mm	Angled	67 mm
Straight Lymphatic Mapping Probe	14 mm	Straight	67 mm
Superficial Head and Neck Probe	11 mm	Straight	53 mm
Abdominal Probe (See also Note 1.)	10 mm	Straight	310 mm
Daniel Probe (See also Note 1.)	10 mm	Angled	310 mm
Thoracic Probe (See also Note 1.)	10 mm	Straight	190 mm
Note 1: The Abdominal Probe, Daniel Probe, and Thoracic Probe also apply to laparoscopic and thoracoscopic use.			
FOR EACH PROBE			
Energy Range	27 – 364 keV		
Tip	Contains detector element, radiation shielding, and radiation collimation		
Probe Sterilization	Ethylene oxide, or use in a sterile drape		

Cable

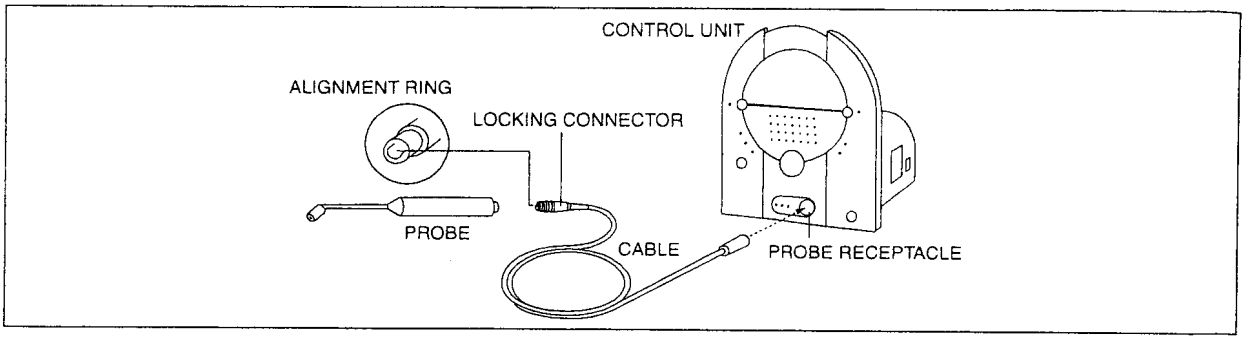
LOCKING CONNECTOR

The PROBE and CABLE connect by means of a locking connector. There is a female plug on the cable and a male receptacle on the probe. Tension on the cable will not pull the cable from the probe.

To disconnect the cable from the probe, grasp the connector near the probe and pull the plug from the probe. Tension on the connector retracts the locking mechanism and allows the plug to be removed from the receptacle.

To connect the cable to the probe, lightly insert the cable plug into the probe, rotate the probe to assure alignment with the plug, and push the plug into the receptacle. A slight audible click may be heard when the CABLE locks to the PROBE.

Cable Features



Power Pak

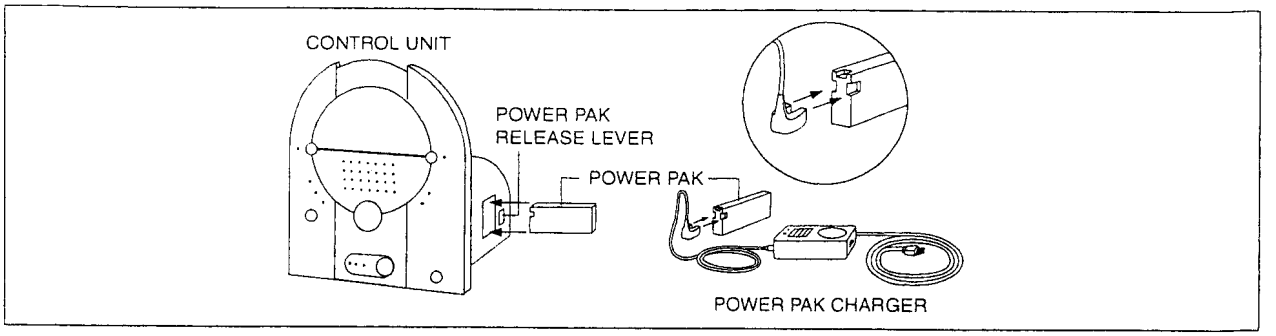
The power pak supplied with the NAVIGATOR GPS* System is a sealed power pak with a nominal voltage rating of 12 volts and a capacity of 2.0 Ampere-hours. The construction of the power pak includes a special shape to ensure proper alignment with and connection to the CHARGER. Use only the NAVIGATOR GPS* power pak supplied with the system, or those certified by the system manufacturer as suitable for use on the NAVIGATOR GPS* System.

Charger

The CHARGER supplied with the NAVIGATOR GPS* System charges one POWER PAK. This takes less than three hours In the United States, the charger has a rating of a patient proximity charger and when used in the operating room, the charger should be at a distance of six feet or greater from the patient. The input to the CHARGER is a detachable, country-specific, line cord. The CHARGER senses the input line voltage within its rated range of 100-240 VAC, 50-60 Hz. The CHARGER output is provided through a cable which terminates in a special connector which is constructed so as to orient in a specific polarity with the power pak. When the charger is receiving electrical power and is properly connected to the power pak, the charger status light, which is yellow in color, indicates the state of the charge.

Status Light	Indicates
Off	Power Pak Absent, or Fully Charged
On	Charging

Power Pak and Charger Features



WARNING: DURING SYSTEM USE, MAINTAIN ELECTRICAL ISOLATION OF THE PATIENT. DO NOT CONNECT EITHER THE PROBE, THE CABLE, OR THE INTERNAL CIRCUIT OF THE CONTROL UNIT TO EARTH GROUND, OR TO OTHER VOLTAGE POTENTIALS.

WARNING: DO NOT DEFEAT THE ELECTRICAL ISOLATION PROVIDED BY THE SURFACE OF THE PROBE CABLE AND THE HOUSING OF THE CONTROL UNIT. THESE ITEMS ISOLATE OTHER VOLTAGE POTENTIALS FROM THE BATTERY-POWERED CIRCUIT INSIDE THE CONTROL UNIT, THE INSIDE OF THE PROBE CABLE, THE SURFACE OF THE PROBE, AND THE PATIENT.

WARNING: DO NOT DEFEAT THE ELECTRICAL ISOLATION BETWEEN THE EXTERNAL DATA PORT ON THE CONTROL UNIT AND THE CIRCUIT INSIDE THE CONTROL UNIT. THE EXTERNAL DATA PORT CAN BE CONNECTED TO EARTH GROUND. THE ELECTRICAL ISOLATION BETWEEN THE DATA PORT AND THE INTERNAL CIRCUIT OF THE CONTROL UNIT MAINTAINS PATIENT ISOLATION.

WARNING: WHEN OPTIONAL SYSTEM COMPONENTS ARE USED WITH THE SYSTEM, MAINTAIN PROBE AND PATIENT ELECTRICAL- ISOLATION FROM EARTH GROUND, AS DESCRIBED BY THIS AND OTHER PRECAUTIONS IN THE OPERATING MANUAL. THESE OPTIONAL COMPONENTS INCLUDE THE COPILOT* DEVICE, THE GAMMA PROBE DRAPE, AND THE CUSTOM CART.

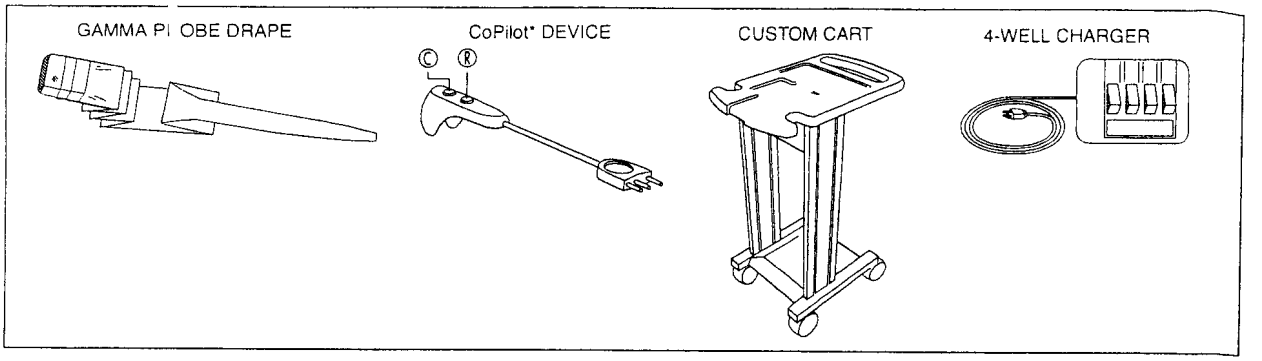
WARNING: THE CHARGER HAS A RATING IN THE UNITED STATES OF A "PATIENT PROXIMITY CHARGER" AND WHEN IT IS USED IN THE OPERATING ROOM, THE CHARGER MUST BE AT A DISTANCE OF GREATER THAN SIX FEET FROM THE PATIENT.

NOTE: Use only the POWER PAK supplied with the NAVIGATOR GPS* System, or a replacement POWER PAK recommended by the manufacturer. Among other characteristics, this POWER PAK includes a keyed connector which mates to the CONTROL UNIT.

NOTE: The POWER PAK supplied with the NAVIGATOR GPS* System is a sealed, lead-acid POWER PAK. If this POWER PAK requires disposal, either return the POWER PAK to the distributor, or recycle the POWER PAK locally, in a manner appropriate for sealed, lead-acid batteries.

NOTE: Use only the CHARGER supplied with the NAVIGATOR GPS* System. This charger includes a keyed connector which mates to the Control Unit and is equipped with special circuitry which preserves POWER PAK life.

System Accessories



SYSTEM ACCESSORIES available for use with the system include a GAMMA PROBE DRAPE, CoPilot* DEVICE, CUSTOM CART and 4-WELL CHARGER. These accessories are not traceable to the manufacturer of the system. These accessories and their use are not described in this manual. Their interaction with the system is described here.

Gamma Probe Drape

An optional, SYSTEM ACCESSORY of a GAMMA PROBE DRAPE is available to provide a disposable, sterile barrier around the PROBE and CABLE.

CoPilot* Device

The optional, SYSTEM ACCESSORY of a CoPilot* Device initiates counting periods and changes the audible RANGE. The CoPilot* Device includes two small buttons, and a long, small-diameter cable which extends to the CONTROL UNIT.

Count Button

On the CoPilot* Device, the "C" button is the COUNT button.

A one second count is obtained by pushing and releasing this button once. A ten second count is initiated by pushing this button twice, in quick succession. The total is shown in the DISPLAY on the CONTROL UNIT and is also downloaded automatically by the CONTROL UNIT through the DATA PORT.

The COUNT INDICATOR on the control unit illuminates during the counting period. The CONTROL UNIT gives an audible indication at the end of the counting period.

Range Button

On the CoPilot* Device, the "R" button is the RANGE button. This button operates the RANGE control on the CONTROL UNIT. Push and release the RANGE button to select an audible range, appropriate to the signal detected by the system.

Connector

The unique CONNECTOR on the CoPilot* Device aligns the CONNECTOR to the CONTROL UNIT in only one orientation. Slide the connector securely into the CoPilot* Device INPUT receptacle on the CONTROL UNIT.

Custom Cart

An optional SYSTEM ACCESSORY of a CUSTOM CART is available for use with the system. The CUSTOM CART locates and orients the CONTROL UNIT at a convenient position for viewing and use, and provides safe, secure storage for probes and accessories.

4-Well Charger

The optional SYSTEM ACCESSORY of a 4-WELL CHARGER allows the simultaneous charge of up to four POWER PAKS.

4 Use

Set Up

The NAVIGATOR GPS* System may be prepared for use in the sterile field by one of two methods: by use of sterile probe drape or ethylene oxide sterilization.

Use of Probe and Cable in a Sterile Drape

1. Fully charge a POWER PAK and place it properly in the CONTROL UNIT.
2. Place the control unit POWER switch in the OFF position.
3. Connect the PROBE to the CABLE. After alignment and proper connection, one click is heard from the connector's locking mechanism.
4. Connect the CABLE to the CONTROL UNIT. Align the plug on the cable with the receptacle on the CONTROL UNIT. Slide the connector into the CONTROL UNIT. One click is heard from the connector's locking mechanism.
5. Wipe the probe and cable with a soft cloth moistened with ethyl or isopropyl alcohol (70% concentration). (See Cleaning, Disinfection, and Sterilization.)
6. Pass the probe into the sterile drape and visually inspect the sterile probe drape to ensure its integrity.
7. Adjust the control unit controls as desired according to the Controls and Specifications section.
8. Turn ON the power switch on the control unit.

Connecting Probe and Cable

The probe and cable connect by a locking connector. There is a female plug on the cable and a male receptacle on the probe. Tension on the cable will not pull the cable from the probe.

To *disconnect* the cable from the probe, grasp the connector near the probe and pull the plug from the probe. Tension on the connector retracts the locking mechanism and allows the plug to be removed from the receptacle.

To *connect* the cable to the probe, lightly insert the plug into the receptacle, rotate the plug to assure alignment of the plug with the receptacle, and push the plug into the receptacle. A slight audible click may be heard when the plug locks in place

Sample, Initial Settings for Technetium-99m

Users adjust the system controls appropriate to the application (see Controls and Specifications). For example, the 140 keV photons of the technetium-99m isotope may be counted by the RMD Standard Lymphatic Mapping Probe (shown below) with these initial settings on the Navigator GPS control unit.

Navigator GPS Setup
for procedure that locates a "sentinel node" labeled with Tc-99m sulfur-colloid

- **Make all electrical connections with "Power Off"**
- **Leave unit in "Scan" mode**
- **Keep ISOTOPE control in "Tc99m" position.**
- **Threshold control "On" (normally) or "Off", surgeon's preference**
- **Range control "X1" (normally), "X10" or "X100", surgeon's preference.**

Uninterrupted Use by Means of Spare Power Pak

Two or more spare POWER PAKS allow uninterrupted use of the NAVIGATOR GPS* System by charging a spare power pak during system use, and placing a freshly-charged power pak in the CONTROL UNIT shortly after the illumination of the control unit's LOW POWER PAK indicator. The LOW POWER PAK indicator signals at least 15 minutes before no useful life remains on the installed power pak. The NAVIGATOR GPS* System has been designed to conserve electrical power and to allow easy changing of the power pak.

To change the POWER PAKS in the CONTROL UNIT

1. On the CONTROL UNIT, press the POWER switch OFF.
2. Place the CONTROL UNIT horizontally on a flat surface.
3. Press the POWER PAK RELEASE lever on the CONTROL UNIT. The POWER PAK will move out approximately 2 centimeters.
4. By hand, pull the POWER PAK the remaining way out of the CONTROL UNIT.
5. Slide a charged POWER PAK into the control unit. The proper orientation is with the POWER PAK terminals directed inside (rather than outside) the control unit , and with the POWER PAK terminals toward the top end (rather than on the bottom end) of the POWER PAK.
6. The POWER PAK RELEASE lever latches when the POWER PAK is in place.
7. On the CONTROL UNIT, press the POWER switch ON.

To charge a POWER PAK in the CHARGER

1. Disconnect the CHARGER from the wall supply.
2. Slide the keyed, charger output plug into the receptacle on the POWER PAK.
3. Plug the CHARGER into the wall outlet. The POWER LED on the Charger will illuminate. The color of the POWER LED is green.
4. The STATUS Light on the Charger shows the condition of charge. The STATUS light is yellow in color.
5. The illumination of the STATUS light indicates the beginning of the charge cycle. The status light stays illuminated during the charge period. The status light goes out when the POWER PAK is charged.
6. The POWER PAK may be kept indefinitely in this charged condition. Alternately, proceed to the next step.
7. Disconnect the CHARGER from the wall power. Disconnect the charger cable from the POWER PAK.

Status Light	Indicates
Off	Power Pak Absent, or Fully Charged
On	Charging

NOTE: **Charge the Power Pak after each use. If the Control Unit has been stored for more than 30 days without a charge, charge the Power Pak before use.**

Concepts

Timed Count

One basic system concept is the comparative measurement of radiopharmaceutical uptake among two or more sites based on a timed count obtained with the probe held in a similar position over each site. To obtain a timed count, the probe is held stationary in position over one site, the COUNT button is pressed and a ten second timed count is acquired. This process is repeated at one or more different sites, or at different angular positions of the probe on the same site, and a comparison is made between the counts obtained at each site.

Continuous Count

A second basic concept is moving, or scanning, the probe across sites and observing the instantaneous system output, principally by means of the PITCH function. The event rate shown in the DISPLAY may also be observed.

Laparoscopic and Thoracoscopic Use

The normal use of a probe is in an open-surgical procedure. The Navigator Probes that may also be applied to laparoscopic and thoracoscopic use have a 10 mm tip diameter and are the following probes:

Name of Probe	Tip Diameter	Angle	Shaft Length
Abdominal Probe	10 mm	Straight	310 mm
Daniel Probe	10 mm	Angled	310 mm
Thoracic Probe	10 mm	Straight	190 mm

When used laparoscopically or thoracoscopically the preparation of the probe, including cleaning, disinfection, and sterilization, and draping of the probe remain the same unchanged from the open surgical preparation of the probe. Specifically when used either laparoscopically or thoracoscopically, the probe and cable should be sterilized before use as described in the Navigator GPS Operator's manual. As with the open surgical use of the device, an appropriate sterile drape may also be used.

The laparoscopic probes are 10 mm in diameter and are designed for use with standard surgical trocars that have at least a 10 mm inner-diameter and feature self-adjusting converters, which allow for the expansion from the probes' minimum to maximum diameters, without loss of pneumo-peritoneum.

NOTE: Please also review the Operating Precautions in this manual concerning the use of a probe in a Laparoscopic or Thoracoscopic procedure.

Data Port

Use of DATA PORT

Immediately following each timed count, the six-digit count total is available from the DATA PORT. The control unit transmits four bytes of data, then returns to normal conditions.

The four bytes are transmitted at a baud rate of 9600 BPS, in an ASCII format. Each byte consists of 10 bits, 1 start bit, 8 data bits, and 1 stop bit. The 8 data bits represent two characters, or digits, in base-16.

The first byte is the count condition. The two characters "CC" signify a one second count, normal data. The characters "DD" indicate a ten second, normal data. EE is one second count, data overflow. FF is ten second sample, data overflow.

The next three bytes is the count total. The six digits start with the least significant digit, and end with the most significant digit. In the data overflow condition (indicated by characters EE or FF in the first byte) the subsequent six digits of the count total have no meaning and should be disregarded.

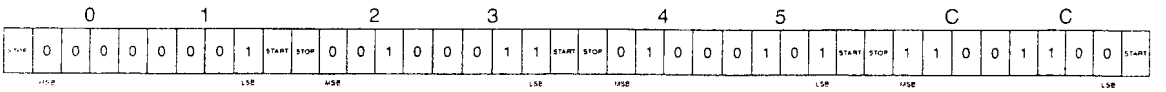
On the DATA PORT, this signal is available on pin number 2. The corresponding electrical ground is on pin number 5. The data structure is illustrated in four examples below, in each example, the count total is 12,345 (twelve thousand, three hundred and forty five).

NOTE: The DATA PORT is "send-only". The NAVIGATOR GPS System* is not constructed to "receive" any information through the DATA PORT.

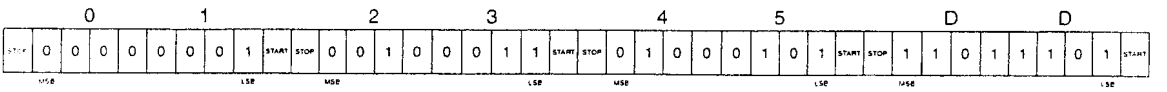
NOTE: In the data overflow condition (indicated by either character EE or character FF in the first byte, the subsequent six digits of the count total have no meaning and should be disregarded).

Examples of DATA PORT Output

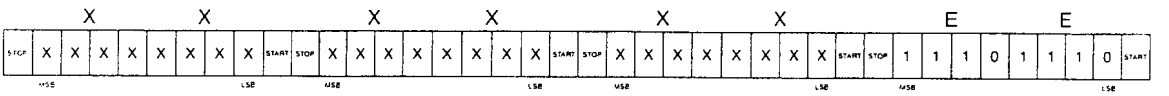
- CC 45 23 01 = 1-SEC sample and count = 12345
  Serial Data out


0 1 2 3 4 5 C C
START 0 0 0 0 0 0 0 1 STOP START 0 0 1 0 0 0 1 1 STOP START 0 1 0 0 0 1 0 1 STOP START 1 1 0 0 1 1 0 0 STOP
MSB LSB MSB LSB MSB LSB MSB LSB

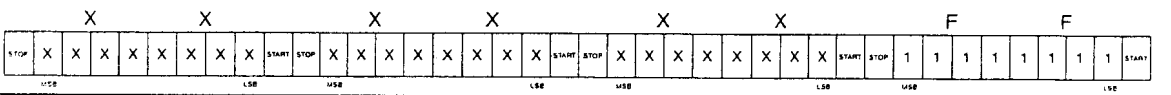
- DD 45 23 01 = 10-SEC sample and count = 12345
  Serial Data out


0 1 2 3 4 5 D D
STOP 0 0 0 0 0 0 0 1 START STOP 0 0 1 0 0 0 1 1 START STOP 0 1 0 0 0 1 0 1 START STOP 1 1 0 1 1 1 0 1 START
MSB LSB MSB LSB MSB LSB MSB LSB

- EE xx xx xx = 1-SEC sample and an overflow has occurred
  Serial Data out


X X X X X X E E
STOP X X X X X X X X START STOP X X X X X X X X START STOP X X X X X X X X START STOP 1 1 1 0 1 1 1 0 START
MSB LSB MSB LSB MSB LSB MSB LSB

- FF xx xx xx = 10-SEC sample and an overflow has occurred
  Serial Data out


X X X X X X F F
STOP X X X X X X X X START STOP X X X X X X X X START STOP X X X X X X X X START STOP 1 1 1 1 1 1 1 1 START
MSB LSB MSB LSB MSB LSB MSB LSB

WARNING: DO NOT DEFEAT THE ELECTRICAL ISOLATION BETWEEN THE EXTERNAL DATA PORT ON THE CONTROL UNIT AND THE CIRCUIT INSIDE THE CONTROL UNIT. THE EXTERNAL DATA PORT CAN BE CONNECTED TO EARTH GROUND. THE ELECTRICAL ISOLATION BETWEEN THE DATA PORT AND THE INTERNAL CIRCUIT OF THE CONTROL UNIT MAINTAINS PATIENT ISOLATION.

5 Cleaning, Disinfecting and Sterilization

Control Unit, Power Pak, and Charger

The control unit and charger may be wiped clean. Use a soft cloth moistened with mild soap and water to avoid scratching or fogging the display window. Dry with a soft cloth. The POWER PAK may be wiped clean with a dry soft cloth.

When not in use, store the control unit in the normal orientation on its mounting feet. Remove the POWER PAK from the control unit for system storage greater than 30 days, transporting the system, or shipping the system.

WARNING: DO NOT CLEAN THE *CHARGER* WHEN THE CHARGER IS CONNECTED TO THE WALL POWER SUPPLY. NEITHER THE *CONTROL UNIT* NOR THE *CHARGER* CAN BE STERILIZED OR IMMERSED IN FLUIDS. ATTEMPTING TO DO SO WILL CAUSE PERMANENT DAMAGE.

Probe and Cable

The probe and cable are reusable devices and are used in a sterile field. Between the uses of the probe and cable in a sterile field, the probe and cable proceed through four recommended stages of activity. These stages of activity are:

1. Immediately after use
2. Cleaning, Disinfection, and possibly Sterilization
3. Storage
4. Immediately before use

In addition, the probe and cable may occasionally be withdrawn from storage and used for activities not in the sterile field. Following these activities, the PROBE and CABLE should be restored to the level of cleaning, disinfection, and sterilization appropriate for their next use in the sterile field.

STEP 1 Immediately After Use

Disconnect the cable from the control unit. Keep the cable connected to the probe. Wipe all visible soil from the probe and cable with a clean sponge moistened with distilled water. Wipe the probe and cable with a soft cloth moistened with ethyl or isopropyl alcohol (70% concentration). Loosely coil the cable (approximately 6 coils) and place the probe and cable in a plastic container for protection during transport to STEP 2.

STEP 2 Cleaning and Disinfecting

The probe and cable may be cleaned and disinfected in accordance with the methods described in STEP 2.

All components, which are used in the operating field, should be cleaned and rinsed prior to reuse with a sterile drape, and prior to sterilization by ethylene oxide. Exercise universal, general precaution when handling components that have been in contact with blood or tissue.

First, remove the probe and cable from the plastic bag of STEP 1. Discard the plastic bag. With the cable still attached to the PROBE, rinse the outside surfaces with a brisk stream of tap water and wipe with a soft cloth soaked in an enzymatic detergent solution (suitable for surgical instruments) for approximately 30 seconds. Visually inspect the probe and cable for contamination. Repeat this cleaning and rinsing procedure until visual inspection reveals no contaminated areas.

Second, detach the cable from the probe. The connector end of the probe and cable should be swirled intermittently in 100 milliliters of enzymatic detergent solution for at least one, but no more than two minutes.

Third, after swirling the end of the probe and the end of the cable in the enzymatic solution, rinse both ends in a brisk stream of tap water for approximately 30 seconds. Dry each connector with a soft cloth.

Store the disinfected probe and cable in separate clean plastic bags (or in a similar fashion) which maintains the cleanliness accomplished here.

STEP 2A Radioactive Decontamination Procedure OPTIONAL

An increase in background counts may signal radioactive contamination of the environment, or PROBE. By a process of elimination, determine if the PROBE is contaminated with radioactive material on its surface. Decontaminate using standard Nuclear Medicine department techniques which may involve washing the PROBE with a solution such as Radiacwash (TM) and a soft gauze pad. Do not contaminate other items with the used, cleaning solution. Dispose of pads and cleaning solution in approved containers. Pay attention that recesses, crevices, and mating surfaces are clean. Do not scratch or abrade the PROBE surface, this may make future decontamination more difficult, or impossible.

STEP 2B Ethylene Oxide Sterilization

If the probe and cable are used in procedures without a sterile, surgical drape, then the probe and cable should be sterilized by ethylene oxide (ETO) gas sterilization described in this STEP 2B.

Prior to ethylene oxide sterilization, the probe and cable should be inspected to ensure that:

- PROBE and CABLE have been cleaned per STEP 2
- the connectors are completely dry
- the cable is free of cracks or cuts

The cable should be loosely coiled (approximately 6 coils) and placed together with the probe and a chemical indicator on a 30" x 30" wrapper. Sequentially wrap using the envelope method and secure the closure with a piece of ethylene oxide chemical indicator tape label NAVIGATOR GPS* System and initial. After sterilization, store the probe and cable in the sterile bag.

A Sterility Assurance Level (SAL) of 10^{-6} was achieved in a hospital recommended cycle for ethylene oxide sterilization following the AAMI TIR No. 12, 1994 protocol. Oxyfume 2002 TM (Allied Signal) was used in the validation study and is 10% ETO, 90 %HCFC.

STEP 2B Ethylene Oxide Sterilization...*continued* PROBE and CABLE RECOMMENDED PARAMETERS for ETHYLENE OXIDE (10% ETO; 90% HCFC) STERILIZATION		
ETO PHASE	**PARAMETER**	**VALUE**
Preconditioning	Temperature Humidity Time	130 ± 5°F 40 - 80% 30 minutes
Sterilization	Initial Vacuum Temperature Gas Concentration Gas Exposure Set Point Humidity Time	26 ± 1 inches Hg 130 ± 5°F 600 ± 50 mg/L 12 ± 1 P.S.I.G. 40 - 80% 120 minutes
Post-Exposure	Vacuum Air Wash	26 ± 1 inches Hg, 3 intervals 20 minutes
Aeration	Time Temperature	12 hr @ 122-135°F, or 24 hr @ room temperature

STEP 3 Storage

Store the probe by suitable means to preserve the integrity of the system.

STEP 4 Preparation Immediately before Sterile Drape

If the probe has not been contaminated by contact with blood or tissue, the probe and cable can be swabbed with alcohol as described here in STEP 4 and inserted into a sterile surgical drape.

Before inserting the probe and cable into the sterile drape, wipe the probe and cable with a soft cloth moistened with ethyl or isopropyl alcohol (70% concentration). Visually inspect the sterile drape before use to ensure its integrity.

WARNING: DO NOT PLACE EITHER THE *PROBE* OR THE *CABLE* IN AN AUTOCLAVE. TEMPERATURES IN EXCESS OF 140°F (60°C) WILL DAMAGE THE PROBE AND MAY DAMAGE THE CABLE.

WARNING: STERILIZE THE *PROBE* AND *CABLE* ONLY WITH ETHYLENE OXIDE. DO NOT STERILIZE WITH *STERIS, STERRAD*, OR *PLAZLYTE*™. OXIDIZING AGENTS MAY BE HARMFUL TO THE PROBE AND CABLE.

WARNING: DO NOT SOAK THE *PROBE* OR *CABLE* IN WATER OR CLEANING SOLUTIONS. DOING SO MAY PERMANENTLY DAMAGE THE PROBE OR CABLE. USE A SOFT BRUSH DURING CLEANING TO AVOID ABRASION OF PROBE SURFACES.

NOTE: For intraoperative use of the NAVIGATOR GPS* System, a sterile surgical drape is recommended.

6 Maintenance

Calibrate Function

The SYSTEM is virtually maintenance free. The PROBE uses inherently-stable, solid-state sensor technology and solid-state electronics, which do not require periodic high voltage adjustments of the CONTROL UNIT to compensate for a gain "drift" associated with photomultiplier tubes. At the factory, the probe and control unit are manufactured to reference standards. In the field, the low-voltage, solid-state technology maintains consistent performance.

The CONTROL UNIT has an internal circuit that demonstrates the factory-set, system gain calibration when connected to a CABLE and PROBE.

The calibration check is frequently performed by an individual in a nuclear medicine department. The 122 keV energy peak of the cobalt-57 isotope is used as the reference standard. The precision of the system allows the user to sometimes also observe lower energy peak regions, such as 60-80 keV x-ray fluorescence peaks of shielding materials used during the test. Knowledge of their presence is required to distinguish these from the 122 keV peak of the cobalt-57 isotope.

One may choose from two tests: the **quick test** and the **long test.** Both tests are easy to understand.

Quick Test

The quick test takes a few minutes to perform. The results usually confirm that the system is in calibration.

Long Test

The long test takes more time, and may be performed if the quick test provides uncertain results. The long test quantifies the consistency of the location of the source to the probe tip. The long test invariably demonstrates system calibration. In the unlikely event that help is needed after performing the long test, contact the distributor of the system.

Quick Test

1. Clean the PROBE and CABLE as described in this manual.
2. Charge the POWER PAK, and install it properly into the CONTROL UNIT, as described in this manual.
3. Place the system controls as indicated in the table titled: System Configuration - Calibration Test.
4. Align a cobalt-57 source directly with the probe tip. Maintain this exact position between the source and the probe tip for the remainder of the test.
5. Place the CALIBRATE control in the CENTERED position, which is indicated by the following symbol on the CALIBRATE control (▸0◂). Press the COUNT control to obtain a ten second count. Record this total.
6. Place the CALIBRATE control in the BELOW position which is indicated by the following symbol on the CALIBRATE control (−). Obtain a ten second count. Record this total.
7. Place the CALIBRATE control in the ABOVE position which is indicated by the following symbol on the CALIBRATE control (+). Obtain a ten second count. Record this total.
8. The highest count should be when the CALIBRATE control is in the CENTERED (▸0◂) position. The count in the ABOVE (+) position and the count in the BELOW (−) position should be less than the count in the CENTERED (▸0◂) position. The observation of this relationship confirms that the system is in calibration.
9. Return the CALIBRATE control to the SCAN position.
10. Return the other system controls to the settings for normal use.
11. End of Test.

NOTE: Because the system is designed to detect slight changes in the location and intensity of radioisotopes, the test source must be maintained in the same direct alignment and distance from the probe tip throughout the calibration tests.

NOTE: The front panel CALIBRATION INDICATOR blinks off and on when the CALIBRATE control is in either the BELOW (−), CENTERED (▸0◂), or ABOVE (+), test position. The CALIBRATION INDICATOR is OFF when the CALIBRATION control is in the SCAN position.

NOTE: When the CALIBRATE control is in either the BELOW position (−), the CENTERED position (▸0◂) or the ABOVE position (+), the CONTROL UNIT automatically disables the ISOTOPE control and the THRESHOLD control. These controls are enabled when the CALIBRATE control is returned to the SCAN position.

System Configuration - Calibration Test

Setting	Item
NAVIGATOR GPS* Probe	connected to PROBE input
ON	POWER switch
Varies	CALIBRATE control (rear panel)
as desired	VOLUME control
as desired	RANGE control
no effect	ISOTOPE control (rear panel)
no effect	THRESHOLD control

System Configuration - Cobalt-57 Alignment

Setting	Item
NAVIGATOR GPS* Probe	connected to PROBE input
(▸0◂)	CALIBRATE control (rear panel)
technetium-99m	ISOTOPE control (rear panel)
OFF	THRESHOLD control
ON	POWER switch
as desired	RANGE control
as desired	VOLUME control

Long Test

1. Clean the PROBE and CABLE as described in this manual.
2. Charge a POWER PAK, and install it properly into the CONTROL UNIT, as described in his manual.
3. Place the system controls as indicated in the table titled: System Configuration - Cobalt-57 Alignment.
4. Align the cobalt-57 source directly with the probe tip and at a distance such that the total shown in the system display is in the range of 2,000 to 10,000 counts per second. For the remainder of the test, **maintain this exact position** between the source and the probe tip.
5. Press the COUNT control to obtain a 10 second count. Record this value of the cobalt-57 ten-second count at the beginning of the test.
6. (Optional) Take additional readings to observe that count totals repeat, statistically.
7. Place the system controls as indicated in the table titled: System Configuration - Calibration Test.
8. Place the CALIBRATE control in the CENTERED (▸0◂) position. Press the COUNT control to obtain a ten second count. Record this total.
9. Place the CALIBRATE control in the BELOW (−) position. Obtain a ten second count. Record this total.
10. Place the CALIBRATE control in the ABOVE (+) position. Obtain a ten second count. Record this total.
11. Place the system controls as indicated in the table: System Configuration - Cobalt-57 Alignment.
12. Obtain a 10 second count. Record this value of the cobalt-57 ten-second count at the end of the test.
13. Return the CALIBRATE control to the SCAN position.
14. Return the other system controls to settings for normal use.
15. The cobalt-57, ten-second count at the beginning of the test should be the same as the cobalt-57, ten-second count at the end of the test, except for the statistical variation encountered in each count. In this test, the statistical variation of each count is approximated by its square root. It is unlikely that the two readings are greater than six standard deviations apart:
    (Co-57 start count) less (Co-57 end count) $\leq$ 6 * square root (Co-57 start count)
    Differences greater than six standard deviations may indicate difficulties in the selection of the source and difficulties in the consistency of its alignment with the probe.
16. Compare the values obtained with the CALIBRATE control in each of the three positions of BELOW (−), CENTERED (▸0◂), and ABOVE (+). The highest count should be when the CALIBRATE control is in the CENTERED (▸0◂) position. The count in the ABOVE (+) position and the count in the BELOW (−) position should be less than the count in the CENTERED (▸0◂) position. The observation of this relationship confirms that the system is in calibration.
17. If the results of step 16, are unfavorable, contact your distributor for further advice. Among other information, include the values of the cobalt-57 start count, cobalt-57 end count, and the values at the CALIBRATE INDICATOR positions of BELOW (−), CENTERED (▸0◂), and ABOVE (+).
18. End of Test.

System Sensitivity Factors

The checks indicated below confirm that the system detects radiation and eliminate the principal factors that change the sensitivity.

First, observe normal system detection of an isotope, such as by means of the above calibrate check, or by the presence and absence of signal corresponding to probe movement on, and off of, a radioactive source.

Second, observe that no additional radiation-attenuating material is around the probe tip which may block the probe's field of view. For example a thick piece of metal placed between the probe and radiation source may

absorb some gamma photons and diminish the number of events counted by the system. For reference, a thin layer of plastic has minimal effect when counting technetium-99m photons.

Third, observe that no additional radiation source has contaminated the probe. For example set the ISOTOPE CONTROL to technetium-99m and the THRESHOLD enabled, or on and count for ten seconds. With no additional radiation source present, or in the field of view of the probe, one should observe fewer than 20 counts in 10 seconds.

These quick checks ensure that the system is counting radiation and that factors (radiation shielding and radiation contamination) are not inhibiting reliable system performance.

Changing Fuse

This fuse can be inspected, and replaced if necessary, by the following steps.

1. Turn the Control Unit Power Switch OFF.
2. Rotate counter-clockwise the extended portion of the rear-panel fuse holder and remove the fuse from the unit.
3. If the existing fuse is discolored or blown, replace with a new fuse of the same rating.
4. Restore this new fuse to the unit and secure with a clock-wise rotation of the fuse holder.

The rating for the fuse is given in the Control Unit Specifications chart.

7 Service

WARRANTY

RMD Instruments, LLC ("RMD") warrants to its customers that, subject to the below provisions. The RMD NAVIGATOR GPS* System and Probes will be free from defects in materials and workmanship for twelve (12) months commencing upon the date of shipment from RMD and continuing for the period indicated below. Subject to the below provisions, replacement parts and products are warranted to be free from defects in material and workmanship for a period equal to the balance of the warranty period remaining on the original part or product.

RMD will repair or replace, at its option and without charge, any of the above products which are returned to RMD or its designated repair site, within the applicable warranty period, with prepayment of shipping costs and which are determined by RMD to be defective in materials or workmanship.

Upon request, and subject to availability and RMD's standard loan terms, RMD will loan to its customer RMD NAVIGATOR* System and/or Probe for its use pending any warranty repairs or replacement of the customer's RMD NAVIGATOR GPS* System and/or Probe.

This Limited Warranty does not apply to any product or replacement part or replacement product which has been subjected to any damage as a result of an accident or abuse, or that has not been used and maintained in accordance with the information contained in the literature accompanying the product, or that has been modified, repaired or serviced by any person or company other than RMD or its authorized representative.

RMD's sole liability for any defective product shall be repair or *replacement, as set forth* ***above. RMD shall not be liable to anyone, under any circumstances, for any special, punitive, incidental or consequential damages whatsoever, including without limitation any costs, expenses, lost profits or other losses however designated. Except as stated above, no warranties are expressed or implied, including without limitation any warranties of merchantability or fitness for a particular purpose, and, except as stated above, RMD expressly disclaims all warranties.***

CAUTION: Before using loose packing materials, such as foam pellets, shredded paper, or excelsior, be sure to wrap the component(s) separately in plastic bags or film or other protective wrapping.

RMD NAVIGATOR Gamma Positioning System

Manufactured by RMD Instruments, LLC, Watertown, Massachusetts 02472

Distributed by RMD Instruments, LLC.

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